The experience has been reported to the FDA in communications dated April 19, 2001 on the whole body imaging studies (section IX.C.1.) and March 7, 2002 on the brain imaging studies (section IX.C.2.). In brief, the injected dose was 2.1-3.0 mCi in the whole body imaging studies and 7.1-15.0 mCi in the brain imaging studies. In all of these studies, specific activity was greater than the detectable limit at Yale, 5,000 mCi/μmol. Potential pharmacological effects were examined by performing the following tests shown in the table. Regular blood tests included blood counts, liver and kidney function tests, and thyroid function tests. None of the 25 subjects showed pharmacological effects in a total of 31 scans.

Time	Tests
At the time of screening	Regular blood and urine tests
Baseline (~30 min before injection)	Respiration rate, EKG, blood pressure, and brief psychiatric interview
Within 5 min after injection	Respiration rate, EKG, blood pressure, and brief psychiatric interview
Between 30 and 60 min after injection	Respiration rate, EKG, blood pressure, and brief psychiatric interview
Next day of injection (approximately 24 h later)	Regular blood and urine tests

The whole body imaging studies showed that three organs with greatest doses with 2.4 h urine voiding intervals were urinary bladder wall (0.26 rad/mCi), Lower large intestine wall (0.26), and upper large intestine wall (0.23) (errors in the communication dated April 19, 2001 have been corrected in this communication and the published paper (Fujita, et al, 2002)). Effective dose was 0.095 rem/mCi. The brain kinetic studies with bolus injection showed distribution volume of 48 mL/cm^3 in the thalamus, 21 in the cerebellum, and 30 in the pons, which was compatible with the known distribution of nAChRs in human brain. Bolus plus constant infusion studies showed poor quality of brain image due to low counts. Therefore, bolus injection appeared to be the choice to measure nAChRs in human brain.